

REMARKS

Upon entry of the above amendments, claims 1-15 and 17-27 are pending in the application. Claim 16 is sought to be cancelled without prejudice thereto or disclaimer thereof any subject matter contained therein. Claims 1, 4-14 and 17-22 are sought to be amended. Support for the amendments to claims 1, 4-7, and 14 can be found, for example, in the claims as originally presented. Support for the amendments to claims 8-13 and 17-22 can be found in Applicants' specification, for example, on page 14, first full paragraph; and on pages 17-18. These amendments contain no new matter and their entry is respectfully requested.

I. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 4, 8-13 and 17-22 are rejected for allegedly being indefinite. Office Action, pages 2-3. Applicants respectfully request that the Examiner reconsider and withdraw the rejection in light of the amendments shown above.

Claim 6 is also rejected for allegedly being indefinite. Office Action, pages 2-3. In particular, the Examiner alleges that "[i]t is unclear what the intended difference is for 'live' and 'attenuated live'" *Id.* at page 3. Applicants respectfully disagree with this rejection and point out to the Examiner that the skilled artisan would recognize the differences between a vaccine based upon a "live" virus versus a vaccine based upon an "attenuated" virus. In contrast to vaccines of attenuated viruses, a vaccine based upon a live virus includes, for example, viruses that are not endemic to the species but can replicate and confer immunity to the species. For example, a virus that normally infects and causes disease in rabbits may be used to confer immunity to cats (without causing disease in cats). Such a vaccine is based upon a "live" virus. Since these terms are well known and understood to the skilled artisan, Applicants respectfully request that the examiner reconsider and withdraw this rejection.

II. Rejections Under 35 U.S.C. § 102(e)

Claim 1 is rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Audonnet *et al.* (U.S. Pat. No. 6,159,477). Office Action, page 4. Solely to advance prosecution and not in acquiescence to the rejection, Applicants have amended claim 1 and believe this rejection is now moot.

III. Rejections Under 35 U.S.C. § 102(b)

Claim 14 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by either Waner *et al.* (*Vet. J.* 155(2): 171-175 (1998)) or Poulet *et al.* (*Vet. Rec.* 148(22):691-695 (2001)). Office Action, page 4. Applicants traverse the rejection.

As amended, claim 14 is directed to a method of vaccinating a puppy against canine herpesvirus (CHV), canine rotavirus (CRV), and Canine Parvovirus (CPV), selected from the group consisting of Minute virus of canine (MVC, CPV-1) and Canine Parvovirus (CPV-2) comprising the steps of administering a vaccine to the bitch prior to whelp comprising a CHV antigen, a CRV antigen, and a CPV antigen and allowing at least one of the puppies to nurse within about forty-eight (48) hours of whelp.

In order for a publication to anticipate a claim under 35 U.S.C. §102(b), the applied reference must teach every element of the claim. *See* M.P.E.P. 8th ed., §2131 (revised October 2005). Here, neither Waner *et al.* or Poulet *et al.* teach every element of the claim as amended.

Accordingly, Applicants request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §102(b).

IV. Rejections Under 35 U.S.C. § 103(a)

Claims 1-7, 14-16 and 23-27 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over the combination of Poulet *et al.*, Mochizuki *et al.* (*J. Vet. Med. Sci.* 65(5): 573-575 (2001)), Miller *et al.* (U.S. Pat. No. 6,057,436), Schwartz *et al.* (*Virology* 32(2):219-223 (Oct. 2002)), and Pratelli *et al.* (*J. Vet. Med. B* 47:273-276 (2000)). Office Action, pages 5-6. Applicants respectfully traverse this rejection.

The M.P.E.P. states the requirements for setting forth a rejection under 35 U.S.C. § 103(a):

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there *must* be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) *must* teach or suggest all the claim limitations.

M.P.E.P. 8th ed., §2143 (revised October 2005) (emphasis added). Hence, among other requirements, there *must* be a suggestion or motivation to combine the references and the combined references *must* teach or suggest all of the claim limitations.

A. *Claims 1-7, 14-16 and 23-27*

Claims 1-6 and 27 are composition claims. Among other recited limitations, claim 1 (as well as its dependent claims 2-5) recite a multivalent vaccine comprising antigen that is Minute virus of canine (MVC). Among other recited limitations, claim 27 (as well as its dependent claim 6) recite a multivalent vaccine comprising CHV, CRV and CPV antigens.

In contrast, claims 7 (as amended), 14-16 and 23-26 are *method* claims. Among other recited limitations, claims 14 and 25 (as well as their respective dependent claims) recite a method of vaccinating a puppy against CHV, CRV and CPV by i) administering a trivalent vaccine comprising CHV, CRV and CPV antigens to a pregnant bitch (*i.e.*, prior to whelp), and ii) allowing the puppies from that bitch to nurse within 48 hours of whelp or otherwise administering colostrum to the puppies within 48 hours of whelp. Hence, all of the method claims are directed to vaccinating puppies to protect them from three different diseases by administering a trivalent vaccine to a pregnant bitch prior to whelp.

1. *The References Fail to Teach Every Claim Limitation*

Applicants respectfully traverse the rejection of claims 1-7, 14-16 and 23-27 on the grounds that the applied references do not teach or suggest all of the claimed limitations. With respect to the composition claims, none of the references teaches or suggests a multivalent vaccine comprising MVC (as required by claims 1-5) or a multivalent vaccine comprising CPV,

CRV and CHV antigens (as required by claims 6 and 27). With respect to the method claims, none of the applied references teach or suggest protecting puppies by administering a multivalent vaccine comprising CPV, CRV and CHV antigens to a pregnant bitch prior to whelp (as required by claims 7-26).

Poulet *et al.* is limited to describing a vaccination protocol using a monovalent CHV vaccine, and fails to mention vaccines based on other antigens (such as CRV or CPV). Thus, Poulet *et al.* does not teach or suggest the claimed multivalent vaccine or methods of administering the claimed multivalent vaccine.

Mochizuki *et al.* is merely an epidemiological study that identifies CRV and CPV-2 in canine stool samples. This publication fails to describe any vaccines based upon CRV, CPV or CHV. Thus, Mochizuki *et al.* also fails to teach or suggest the claimed multivalent vaccine or methods of administering the claimed multivalent vaccine.

As evident from the excerpt referenced by the Examiner in the rejection, Miller *et al.* at best mentions a bivalent vaccine comprising canine corona virus. Even if the Examiner were to deem such mentioning as being an enabling teaching, this patent does not describe CHV, or a trivalent vaccine comprising CHV, CPV and CRV. Nothing in the excerpt relied upon by the Examiner would suggest to the skilled artisan the claimed multivalent vaccine or methods of administering the claimed multivalent vaccine.

Schwartz *et al.* is merely a genetic study comparing MVC to the CPV family. This publication does not mention vaccines of MVC or CPV. This publication also does not discuss CRV or CHV, or vaccines comprising antigens from these viruses. Hence, Schwartz *et al.* fails to teach or suggest the claimed multivalent vaccine or methods of administering the claimed multivalent vaccine.

Pratelli *et al.* is limited to a discussion of vaccinating puppies with CPV-2. This publication does not refer to CHV or CRV, or multi- or trivalent vaccines. Hence, Pratelli *et al.* fails to teach or suggest the claimed multivalent vaccine or methods of administering the claimed multivalent vaccine.

Hence, none of the references alone or in combination teach or suggest all of the claim limitations.

2. *No Suggestion or Motivation to Combine References*

Applicants respectfully traverse the rejection of claims 1-7, 14-16 and 23-27 on the grounds that there is no suggestion or motivation to combine the references. In particular, Pratelli *et al.* teaches away from Poulet *et al.* Based upon the abstract provided by the Examiner, Poulet *et al.* appears to be directed to protecting puppies against CHV-1 by administering to their dams a monovalent vaccine against CHV-1 prior to whelp. Passage of maternal antibodies against CHV-1 from the dam to the puppies apparently confers protection against CHV-1 associated disease caused by CHV-1.

In contrast with Poulet *et al.*, Pratelli *et al.* regards maternally derived antibodies to be an *impediment* to successful protection of puppies. Pratelli *et al.* states that "[m]aternally derived antibodies (MDA) to CPV may persist in pups to the age of 13 weeks, or more . . . , and they *interfere* with the development of an active immunity following vaccination." Page 274, lines 5-7 (emphasis added); *see also* page 275, first paragraph under "Discussion". Pratelli *et al.* propose overcoming this "interference" by administering a high titer vaccine directly to the puppies at age 5 weeks. *See* "Experimental procedures" on page 274, and "Discussion" on page 275. Because Pratelli *et al.* regarded MDAs to interfere with the ability to protect puppies, this publication teaches away from methods of protecting puppies by administering vaccines to their dams. According to Pratelli *et al.*, administering a vaccine to a pregnant bitch prior to whelp would exacerbate the MDA interference (and consequently exacerbate effective means of protection against viruses) in puppies. Hence, there is no suggestion or motivation to the skilled artisan to combine Poulet *et al.* with Pratelli *et al.*

Moreover, there is no suggestion or motivation to the skilled artisan to combine either of these publications with Mochizuki *et al.* or Schwartz *et al.* (which are respectively merely epidemiological or genetic studies that make no reference to vaccines or vaccination protocols).

B. Claims 8-13 and 17-22

Claims 8-13 and 17-22 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over the combination of Poulet *et al.*, Mochizuki *et al.*, Schwartz *et al.*, and Pratelli *et al.*, as applied to claims 6, 7, 14-16 and 23-27 above, and further in view of Willem *et al.* (*Rev. de Medecin Vet.* 152(5): 373-378 (2001)). Office Action, page 9. Applicants respectfully traverse the rejection.

For the reasons described above and fully incorporated here, none of the applied publications teach or suggest all of the limitations as recited by Applicants' claims. Moreover, there is no suggestion or motivation to the skilled artisan to combine Poulet *et al.* with Pratelli *et al.*, or either of these publications with Mochizuki *et al.* or Schwartz *et al.* Furthermore, for reasons set forth below, Willem *et al.* does not cure the deficient teachings of Poulet *et al.*, Mochizuki *et al.*, Schwartz *et al.*, and Pratelli *et al.*

Willem *et al.* is directed to vaccination of 4-8 week old puppies with a CPV vaccine. As with Pratelli *et al.*, Willem *et al.* is concerned with avoiding problems arising from maternally derived antibodies that interfere with the efficacy of vaccines. See "Introduction" at page 373 and the second paragraph of the "Conclusion" on page 378. Willem *et al.* is interested in a "reduction in the critical period," *i.e.*, the period in which maternally derived antibodies interfere with vaccines. Hence, Willem *et al.* teaches away from administering vaccines of any sort to a pregnant bitch, as recited by Applicants' claims. Thus, there is no motivation or suggestion to combine Willem *et al.* with Poulet *et al.*, as the latter appears to pertain to protection of puppies against CHV by administering a pregnant bitch with monovalent CHV vaccine. Furthermore, there is no suggestion or motivation to the skilled artisan to combine Willem *et al.* with Mochizuki *et al.* or Schwartz *et al.* (which are respectively merely epidemiological or genetic studies that make no reference to vaccines or vaccination protocols).

Moreover, Willem *et al.* does not teach a multivalent vaccine comprising CPV, CRV and CHV antigens. Hence, there is no proper combination of Willem *et al.* with any of the other applied publications that teaches or suggests all of the claim limitations.

Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

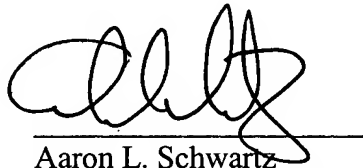
USSN: 10/539,670
Attorney Docket: I-2002.025 US
Response to Office Action of June 29, 2006

Conclusion

Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. 02-2334.

Applicants submit that this application is in condition for allowance, and request that it be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'A. Schwartz', written over a horizontal line.

Aaron L. Schwartz
Registration No. 48,181
Patent Counsel

Patent Department
Intervet Inc.
P.O. Box 318
29160 Intervet Lane
Millsboro, DE 19966
(302) 933-4034 (tel)
(302) 934-4305 (fax)